

Remarks

Reconsideration of the subject application is requested in view of the preceding amendments and the following remarks. Claims 1-31 were in the application. Claims 18-30 have been previously withdrawn from consideration. By this amendment, claims 1, 7, 9 and 31 are amended, and new claims 32-34 are submitted for consideration. Upon entry of this amendment, claims 1-34 are in the application.

Support for new claims 32-34 and the amendments to claim 1, 7, 9 and 31 can be found in the specification. No new matter is introduced.

I. Objections to claim 7

Claim 7 stands objected as to missing a closing parentheses “)” after "poly (DL-lactic acid". Claim 7 is hereby amended to correct this typographical error.

II. Rejections of claims 3-6 under the second paragraph of 35 U.S.C § 112

Claims 3-6 stand rejected as allegedly indefinite under 35 U.S.C § 112, second paragraph for reciting the term “average molecular weight” without specifying whether it was the number average molecular weight or the weight average molecular weight. This rejection is traversed. Applicants acknowledge the existence of several different forms of definition of molecular weight, including the number average molecular weight and the weight average molecular weight. However, the existence of multiple specialized terms does not necessarily render a more generic term indefinite. The law regarding "definiteness" is not a matter of pure academic accuracy, but is a practical issue and is determined by what those of ordinary skill in the art understand as being claimed. MPEP 2173.02 - Clarity and Precision, for example, has the following guidelines:

“The examiner's focus during examination of claims for compliance with the requirement for definiteness of 35 U.S.C. 112, second paragraph is whether the claim meets the threshold requirements of clarity and precision, not whether more suitable language or modes of expression are available. When the examiner is satisfied that patentable subject matter is disclosed, and it is apparent to the examiner that the claims are directed to such patentable subject matter, he or she should allow claims which define the patentable subject matter with a reasonable degree of particularity and distinctness. Some

latitude in the manner of expression and the aptness of terms should be permitted even though the claim language is not as precise as the examiner might desire. Examiners are encouraged to suggest claim language to applicants to improve the clarity or precision of the language used, but should not reject claims or insist on their own preferences if other modes of expression selected by applicants satisfy the statutory requirement. The essential inquiry pertaining to this requirement is whether the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity. Definiteness of claim language must be analyzed, not in a vacuum, but in light of:

- (A) The content of the particular application disclosure;
- (B) The teachings of the prior art; and
- (C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.

In reviewing a claim for compliance with 35 U.S.C. 112, second paragraph, the examiner must consider the claim as a whole to determine whether the claim apprises one of ordinary skill in the art of its scope and, therefore, serves the notice function required by 35 U.S.C. 112, second paragraph by providing clear warning to others as to what constitutes infringement of the patent. See, e.g., *Solomon v. Kimberly-Clark Corp.*, 216 F.3d 1372, 1379, 55 USPQ2d 1279, 1283 (Fed. Cir. 2000).” MPEP 2173.02

Based on general usage of the terminology and from the particular usage of the terminology in the specification (e.g., ¶¶ 0051, 0052, 0065, 0068 and 0082), it is clear to those of ordinary skill in the art that the average molecular weight as recited in the claims of the subject application refers to the weight average.

In addition, the question of indefiniteness raised by the Office action does not, and cannot, suggest that the description fails to meet the enablement requirement. Rather, the question relates to what Applicants regard as the invention to which they claim. In this regard, the unambiguous statements made in this amendment, together with the general usage of the terminology and the particular usage of the terminology in the specification make the meaning of the claim language clear and definite. Accordingly, Applicants respectfully request the rejections be withdrawn.

III. Claim Rejections over Domb et al. - 35 U.S.C. § 102

Claim 31 was rejected as allegedly being anticipated by Domb et al., (U.S. Pat. No. 6,007,845). With this amendment, claim 31 is amended to recite a thermogelling biodegradable polymer comprising a polyethylene glycol (PEG) block and a biodegradable polyester block, wherein the blocks are linked to form a graft polymer. Domb et al. do not disclose a graft polymer. Both of these explicit additions were already claimed. The "thermocelling" was an inherent characteristic interpreted in view of the specification. The "graft" clarification was already dictated by the claimed formula.

Domb et al. disclose a block copolymer, a structurally different type of polymer than a graft polymer. Both of these explicit additions were already claimed. The "thermogelling" was an inherent characteristic based on the claimed polymer as interpreted in view of the specification. The "graft" clarification was already dictated by the claimed formula. Domb et al. neither teach nor suggest any type of a graft polymer having a backbone and a grafted block, which are characteristic of a graft polymer as recited by claim 31, let alone a graft polymer comprising a PEG block or a biodegradable polyester block as recited in claim 31.

Furthermore, Domb et al. do not disclose a thermogelling polymer. The copolymer particles disclosed by Domb et al. do not and cannot form thermogelling solutions. In fact, the micro and nanoparticles of Domb et al. and the thermogelling solutions presently claimed are mutually exclusive concepts. As known in the art and described in the present application, thermogelling means a property of a material that exists in liquid form (e.g., a solution) at a certain range of temperatures but forms a gel at a different range of temperatures. Domb's particles are not thermogelling as they are insoluble in water. If the Domb polymers were not insoluble, the particles would dissolve when introduced into an aqueous medium, defeating the goal of Domb to create stable particles for the controlled delivery of bioactive materials. (Col. 2, ll. 62-66; col. 4, ll. 15-22; and col. 5, ll. 59-61.) Domb further makes no reference to the effect of temperature on copolymer solubility because the formation of thermogelling solutions neither occurs nor was it contemplated by Domb.

Furthermore, Applicants' claim 31 recites a biodegradable polymer comprising a polyethylene glycol (PEG) block and a biodegradable polyester block, wherein the blocks are

linked to form a graft polymer of a general structure comprising the formula $An(B)$, where n is greater than 2 and A is selected from the group *consisting of* a polyethylene glycol block and a biodegradable polyester block, B is selected from the group *consisting of* a polyethylene glycol block and a biodegradable polyester block, and A is different from B . In contrast, Domb et al. do not disclose a polymer having a polyethylene glycol or biodegradable polyester polymer backbone, much less a graft polymer comprising the specific formula recited in Applicants' claim 31, but instead discloses a hydrophilic polymer and a hydrophobic polymer covalently linked to a "multifunctional compound". (Col. 2, ll. 36-56; col. 3, l. 66-col. 4, l. 9.)

Accordingly, claim 31 is allowable over the art of record.

IV. Claim Rejections over Cha et al. - 35 U.S.C. § 102

Claims 1-15, 17 and 31 were rejected as allegedly being anticipated by Cha et al., (U.S. Pat. No. 5,702,717). This rejection is traversed.

For clarity for the Examiner's understanding, independent claim 1 is amended to recite "a thermogelling biodegradable in aqueous polymer solution, comprising a biodegradable graft polymer..."; independent claim 9 is amended to recite "a biodegradable bioactive agent delivery system comprising... a thermogelling biodegradable aqueous polymer solution comprising a graft polymer..."; and claim 31 is amended to recite "a thermogelling biodegradable polymer comprising a polyethylene glycol (PEG) block and a biodegradable polyester block, wherein the blocks are linked to form a graft polymer..."

Cha et al. do not disclose a graft polymer as recited in the Applicants' claims. Cha et al. disclose a block copolymer (a triblock or multiblock copolymer), a structurally different type of polymer than a graft polymer. Specifically, Cha et al. disclose a biodegradable block copolymer having a hydrophobic polymer block A and a hydrophilic polymer block B . Blocks A and B are linked in formation of block copolymer rather than formation of a graft polymer as claimed in the present application. Cha et al. neither teach nor suggest any type of a graft polymer having a backbone and a grafted block, which are characteristic of a graft polymer as recited by claims 1, 9 and 31.

Independent claims 1, 9 and 31 and their dependent claims 2-8 and 10-17 are therefore allowable over Cha et al. The dependent claims 2-8 and 10-17 are also allowable due to their unique and nonobvious combinations of features.

V. Claim Rejections over Rath et al. - 35 U.S.C. § 102

Claims 1, 3-15, and 17 were rejected as allegedly being anticipated by Rath et al., (U.S. Pat. No. 6,004,573). This rejection is traversed.

Rath et al. do not disclose a graft polymer as recited in the Applicants' claims. Rath et al. disclose a biodegradable ABA-type block copolymer made of a major amount of hydrophobic poly(lactide-co-glycolide) and copolymer A-blocks and a minor amount of a hydrophilic polyethylene glycol polymer B-block. As previously discussed, a block copolymer is structurally different from a graft polymer as recited by Applicants' claims. Rath et al. neither teach nor suggest a graft polymer having a backbone and a grafted block, which are characteristic of a graft polymer as recited by claims 1 and 9.

Independent claims 1 and 9 and their dependent claims 2-8 and 10-17 are therefore allowable over Rath et al.

VI. Claim Rejections over Cha et al. in view of Domb et al. - 35 U.S.C. § 103(a)

Claims 1-17 and 31 were rejected as allegedly being obvious over Cha et al. in view of Domb et al. This rejection is traversed.

First, it appears that the above rejection over Cha et al. in view of Domb et al. is directed to dependent claim 16 instead of claims 1-17 and 31. The Office action states "the instant invention further recites a cell over Cha et al. However, the utilization of the cell as a bioactive agent is well known as taught by Domb et al." Because only claim 16 recites a cell, it is assumed that this rejection is drawn to claim 16.

Claim 16 depends from independent claim 9, which is allowable over Cha et al., Domb et al. or a combination thereof as set forth above. Neither Cha et al. nor Domb et al. teach or disclose a biodegradable graft polymer as recited in claim 9. Claim 16 is therefore allowable over the art of record.

VII. Claim Rejections over Cha et al. in view of Rath et al. - 35 U.S.C. § 103(a)

Claims 1, and 3-17 were rejected as allegedly obvious over Rath et al. in view of Domb et al., Prokop (US20030035838A1) or Cha et al. This rejection is traversed.

First, it appears that the above rejection over Rath et al. in view of Domb et al., Prokop (US20030035838A1) or Cha et al. is directed to dependent claims 11-13 instead of to claims 1-17 and 31. The Office action states "the instant invention further recites various anticancer agents such as taxol and a cell and polyester blocks such as poly (ϵ - caprolactone) over Rath et al. However, the utilization of such agent is well known as taught by Don et al." Because only claims 11-13 explicitly recite anticancer agents, it is assumed that this rejection is drawn to claims 11-13.

Claims 11-13 depend from independent claim 9, which is allowable over Rath et al., Domb et al., Prokop, Cha et al., and any combination thereof. None of the cited references (Rath et al., Domb et al Prokop, and Cha et al.) teach or disclose a biodegradable graft polymer as recited in claim 9. As previously discussed, Rath et al. disclose a biodegradable ABA-type block copolymer that is structurally different from a graft polymer as recited by Applicants' claims. None of the other cited references make up for the deficiency of Rath et al. These references, even if combined, do not teach or disclose a biodegradable graft polymer as recited in claim 9. Claims 11-13 are therefore allowable over the art of record.

VIII. Dependent claims

All rejected dependent claims are allowable for the reasons stated above for the independent claims. Each of the dependent claims is further allowable in view of each claim's unique and non-obvious combination of features.

IX. New claims

New claims 32-34 are submitted for consideration. Claim 32 is an independent claim while claim 33-34 depend from claim 32. Claim 32 recites distinct features of a graft polymer, wherein a polyethylene glycol block forms a part of the backbone of the graft polymer and a polyester block is grafted to the backbone. These features are supported throughout the specification. No new matter is introduced. Claims 32 and its dependent claims 33-34 are allowable over the references of record for reasons similar and the same as those discussed above.

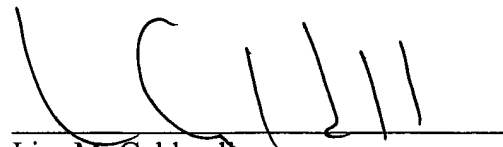
X. Conclusion

For at least the above reasons, it is submitted that all of the elected claims are allowable and early notification to this effect is respectfully requested.

Respectfully submitted,

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By

A handwritten signature in black ink, appearing to read 'Lisa M. Caldwell', is written over a horizontal line.

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